DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94548d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

February 24, 2004

Via Federal Express

Henry E. Green
President and Chief Executive Officer
Obsidian Medical Technology Inc.
7475 Starward Drive, ste. 101
Dublin, CA 94568

WARNING LETTER

Dear Mr. Green:

Our review of information collected during an inspection of your firm's operations located in Dublin, CA, from November 26, 2003 through December 2, 2003, revealed that your firm manufactures image processing systems. These products are devices as defined in Section 201(h) of the Federal, Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) Regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. At the close of the inspection, you were issued a Form FDA-483 which delineated a number of significant CGMP inspectional observations which include, but are not limited to the following:

1. Failure to adequately establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured and that meets the requirements in 21 CFR 820 as required by 21 CFR 820.5. For example, management has not ensured that quality system requirements have been effectively established and maintained.

2. Failure of management with executive responsibility to establish its policy and objectives for, and commitment to, quality as required by 21 CFR 820.20(a).

3. Failure to adequately establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements in 21 CFR 820, as required by 21 CFR 820.20(b). For example, you have failed to appoint a management representative and document such appointment.

4. Failure for management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements in 21 CFR 820 and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c). For example, you have failed to conduct management reviews.

4. Failure to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22.

5. Failure to establish and maintain procedures to control all documents that are required by 21 CFR 820 as required by 21 CFR 820.40.

6. Failure to adequately establish (define, document and implement) and maintain procedures for implementing corrective and preventive actions, which include requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems, as required by 21 CFR 820.100(a)(l).

7. Failure to adequately establish (define, document, and implement) and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, which ensure that complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 or 804 of this chapter, Medical Device Reporting, as required by 21 CFR 820.198(a)(3).

8. Failure of your complaint investigations to include a record of the corrective action taken as required by 21 CFR 820.198(e)(7). For example the "Fix" fields in your Engineer Bug Reports are left blank.

9. Failure of your complaint investigations to include a record of the name, address and telephone number of the complainant as required by 21 CFR 820.198(e)(4).

We acknowledge receipt of your written response dated January 10, 2004. However, your response, while promising corrective actions to our observations, does not provide any details regarding those corrective actions. As such, we are unable to evaluate the adequacy of your proposed corrections.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

You are responsible for investigating and determining the causes of the violations identified by FDA. You also must promptly initiate permanent corrective actions and preventative action on your quality system.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations relating to the subject devices have been corrected.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. Please address your response and any questions to the Food and Drug Administration, San Francisco District, 1431 Harbor Bay Parkway, Alameda, CA 94502, attention: Russell A. Campbell, Compliance Officer.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Mr. Campbell at the above address or at 510-337-6861.

Sincerely yours,

Charles M. Breen
Acting District Director